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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,338	08/23/2001	Hiroyuki Mukai	MUKAI=1	8157

1444 7590 10/27/2003

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EXAMINER	
SIEW, JEFFREY	

ART UNIT	PAPER NUMBER
1637	16

DATE MAILED: 10/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/935,338	Applicant(s) MUKAI ET AL.	
	Examiner Jeffrey Siew	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *221-327* is/are pending in the application.

4a) Of the above claim(s) *280-297 and 318-327* is/are withdrawn from consideration.

5)☐ Claim(s) *301-316* is/are allowed.

6)☐ Claim(s) *221-278,298-300 and 317* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *221-327* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 221-279,298-317, drawn to method of amplification, classified in class 435, subclass 91.2.

II. Claims 280-283, drawn to kit with DNA polymerase, classified in class 435, subclass 6.

III. Claims 284-286, 328-331, drawn to a composition with endonuclease and polymerase, classified in class 435, subclass 183.

IV. Claims 287-290 drawn to chimeric oligonucleotide, classified in class 536, subclass 23.1.

V. Claims 291-296 drawn to method of producing, classified in class 435, subclass 6.

VI. Claims 297,326,327, drawn to a product of a reagent, classified in class 435, subclass 6.

VII. Claim 318, drawn to chimeric primer for detecting enterohermorrhagic E. coli, classified in class 536, subclass 24.3.

VIII. Claim 319, chimeric primer for detecting viroid, classified in class 536, subclass 24.3.

IX. Claim 320, chimeric primer for detecting C. botulinum, classified in class 536, subclass 24.3.

X. Claims 321, chimeric primer for detecting papilloma virus, classified in class 536, subclass 24.3.

XI. Claims 322, chimeric primer for detecting hepatitis virus C, classified in class 536, subclass 24.3.

XII. Claims 323, chimeric primer for detecting S. aureus, classified in class 536, subclass 24.3.

XIII. Claims 324, chimeric primer for detecting M. tuberculosis, classified in class 536, subclass 24.3.

XIV. Claims 325, chimeric primer for detecting Chlamydia, classified in class 536, subclass 24.3.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions Groups (I,V) and Groups (II-IV, VI-XIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products claims of Groups (II-V, VII-X) may be used in a plurality of different methods including sequencing and mutagenesis.

Inventions Group I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case

Group I is drawn to method of amplification which may subsequently be used in sequencing methods while Group V is drawn to a method of producing.

Inventions Group II-IV, VI-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each Group is related to structurally and functionally unrelated product. Group IV is drawn to primer which is composed of deoxyribonucleotide chains. Group III is drawn to DNA polymerase which functionally extends chains and composed of amino acids. Group II is drawn to a kit which combines both polymerase and endonuclease which may be functionally each used together or separately in a plurality of different operations such as sequencing, mutagenesis and cloning. Group VI is product of amplification which is double stranded DNA. Group VII –XIV are each drawn to primers to different specific organisms.

Sequence Election Requirement Applicable to All Groups

3. In addition, Group I,VII-XIV detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. Furthermore, the sequence searching in multiple expansive databases has put undue burden on the examiner and office resources. Office Policy has established that for an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequence (See MPEP 803.04).

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, **up to** ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

4. Claims 280-297,318-327 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper no. 15

Applicant's election with traverse of Group I and SEQ ID NO: 136 in Paper No. 15 is acknowledged.

Claim Objections

5. Claim 238 should employ the term "wherein..." rather than parenthesis to define limitations.

Claim 223 fails to further limit claim 221. A lack of distinction between substantially homologous and complementary fails to further limit claim 223.

Claim 315 the word "consisting" is misspelled.

Double Patenting

6. Claims 298 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 305,307. Claims 301 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 306. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one

claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 221-278 & 300 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) A deficiency in an adequate number of active steps in claim 221 render the claims 221-278 indefinite. It is unclear as to what steps occur in the mixture. While the claims recite DNA polymerase has strand displacement activity and endonuclease that cleaves, it is unclear whether such the enzymes would function to have the strand displacement and cleave in the claim. Nor is it clear as to what order the steps are to occur.

B) In claim 300 it is unclear as to whether the DNA polymerase referred to in the claim is different from the DNA polymerase in claim 298.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 221,223,225,226,277,278,298-300, are rejected under 35 U.S.C. 102(b) as being anticipated by Walder et al (EP 0496483 A2 July 29, 1992).

Walder teach a method of amplifying by preparing a mixture with template, dNTPS, DNA polymerase with strand displacement activity and endonuclease that cleaves extended strand and chimeric primer that is substantially complementary to nucleotide sequence and contains a ribonucleotide on 3' terminal side and dNTP and incubating (see whole doc. esp. page 4 line 11 & 13, page 7 line 4 & figure 2 & claim 14). They teach RNAse H (see page 5 line 5).

The claims do not read on active steps of strand displacement.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 317 is rejected under 35 U.S.C. 102(e) as being anticipated by Kurn (US6,251,639 June 26, 2001).

Kurn teach a method of amplifying a nucleic acid comprises using a DNA polymerase have strand displacement to effect a template switching reaction.

SUMMARY

10. Claims 301-316 are allowable. There is no prior art that teach or suggest the method of amplifying with chimeric primer with ribonucleotide on 3' terminus or 3' terminal side and strand displacement.

CONCLUSION

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

JEFFREY SIEW
PRIMARY EXAMINER

October 19, 2003